



ASP-8

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Zhu, et al. Confirmation No.: 7471
Appln. No. : 09/810,872 Art Unit : 1743
Filed : March 16, 2001 Examiner : Cross, LaToya I.
Title : METHOD FOR RAPIDLY ASSAYING
ALDEHYDE-CONTAINING DISINFECTANT

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APPEAL BRIEF

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I. Real Party in Interest

This application is assigned, via an assignment recorded at reel 12672, frame 929, to Ethicon, Inc. which is owned by Johnson & Johnson.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of the Claims

Claims 1 to 7, 10 to 23, and 25 to 33 are pending in this application. Claims 15 to 23, 25 to 29 and 31 have been withdrawn from consideration. Claims 1 to 7, 10 to 14, 30 and 32 to 33 are before the Examiner and form the basis for this appeal. Presently, claims 1 to 7, 10 to 12, 14 and 30 stand rejected under 35 U.S.C. §102(b) over the Opp U.S. Patent No. 4,471,055. Claim 14 stands rejected under 35 U.S.C. §103(a) over Opp in view of the McAlister et al. U.S. Patent No. 4,703,763. Claims 32 and 33 stand rejected under 35 U.S.C. §103(a) over the Witonsky et al. U.S. Patent No. 4,521,376 in view of the Wu U.S. Patent No. 6,436,716.

IV. Status of Amendments

No amendments have been filed after issuance of the Final Office Action Mailed October 30, 2004.

V. Summary of the Invention

The present invention is drawn to a method of determining the presence of a point of interest of an aldehyde in a test sample which includes the steps of:

1) reacting the aldehyde in the test sample with an amount of a compound that reacts with a carbonyl group of the aldehyde in a first reacting step, wherein said amount is sufficient to react with the aldehyde to the point of interest to produce a first color;

2) reacting a compound having an amino group with any remaining aldehyde in the test sample in a second reacting step, the compound being one that reacts with the aldehyde to produce a second color; and

3) determining the presence of an excess of aldehyde in the test sample to the point of interest by observation of a final color of the test sample. (See specification page 2, line 15 to page 4, line 22, page 6, line 1 to page 8, line 13 and Fig. 1)

In a preferred embodiment, the compound having an amino group is an amino acid. In a more preferred embodiment the amino acid is glycine or lysine. In a preferred embodiment, the compound that reacts with the carbonyl group of the aldehyde is selected from the group including a salt of bisulfite, a salt of cyanide, hydrazine, and hydroxylamine. (See Specification page 7, lines 12 to 28)

In a preferred embodiment, the aldehyde includes a germicide. In a more preferred embodiment, the germicide is selected from the group including OPA, glutaraldehyde, and formaldehyde. (See Specification page 6, line 26 to page 7, line 5)

VI. Issues for Appeal

A. Whether the Examiner has established that Op anticipates claims 1 to 7, 10 to 12, 14 and 30 under 35 U.S.C. §102(b)?

B. Whether the Examiner has established a prima facie case of obviousness regarding claim 14 under 35 U.S.C. §103(a) over Opp in view of McAlister et al.?

C. Whether the Examiner has established a prima facie case of obviousness regarding claims 32 and 33 under 35 U.S.C. §103(a) over Witonsky et al. in view of Wu ?

VII. Grouping of the Claims

For purposes of this Appeal only, the group of claims identified in each rejection stands and falls together.

VIII. Argument

Applicants have discovered a unique method for determining whether an aldehyde solution has sufficient strength. In this method, although the first and second reactions occur essentially sequentially, a user does not have to manually perform these reactions in

sequential order as the chemistry of the first and second reactions handles this automatically. None of the references which were cited in the office action teach or suggest this unique and valuable method.

Applicants submit that the Examiner has failed to establish that claims 1 to 7, 11, 12, 14 and 32 are anticipated by Opp under 35 U.S.C. § 102(b). Opp fails to teach all of the claim limitations. Specifically, Opp does not teach having the first reactant perform its reaction in the presence of the second reactant. Rather, Opp teaches away from such a reaction system. In column 5 starting at line 29, Opp describes how in his invention the reaction rates are similar thus requiring some means for allowing the first reaction to complete before initiating the second reaction. The first reaction is shielded from the second reactant either by manually withholding application of the second reactant or by encasing the second reactant in such a fashion as to prevent its immediate dissolution and thus shielding the first reaction from the presence of the second reactant. Accordingly, Opp cannot anticipate as Opp does not teach the limitation of performing the first reacting step in the presence of the second reactant.

The Examiner asserts that at column 2, lines 24-32 and at column 3, lines 19 to 24, Opp teaches the concept of performing the first reaction in the presence of the second reactant. The first cited section of Opp makes no such teaching. Rather, it describes the overall outcome. Opp later describes the aforementioned shielding of the second reactant to achieve this goal. Accordingly, the first reaction does not occur in the presence of the second reactant. The second cited section of Opp describes reaction kinetics, yet fails to enable such a scenario. No reactants are cited which would fulfill these requirement and the rest of the reference is devoted to ways in which one reactant can be shielded from the other until its reaction is complete. Accordingly, Opp could not be in the prior art under such a theory of anticipation as Opp is not an enabling reference.

Neither would Opp make the claimed invention obvious. Despite the discussion cited in column 3, Opp not only fails to enable such scenario but actually teaches away from

it. All of the examples assume reaction kinetics could only be found which would not allow the first reaction to complete before being adversely affected by the second reactant.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness in rejecting claim 14 under 35 U.S.C. §103 over Opp in view of McAlister. There is no suggestion for making the alleged combination and even if made it would not reach the claimed invention. There is no suggestion in either McAlister et al. or Opp for combining these two references. There is no suggestion in McAlister et al. of utility of its syringe for anything other than drawing blood and those in the aldehyde analyzing arts would not be expected to look to the art of blood sampling for a solution to their problems. However, even if made, the alleged combination fails to reach the claimed invention. McAlister et al. add nothing to the teaching of Opp regarding the step of performing the first reacting step in the presence of the second reactant. Accordingly, the alleged combination fails to teach or suggest the claimed invention.

Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness in rejecting claims 32 and 33 under 35 U.S.C. §103(a) over Witanski et al. and Wu. This combination fails to reach the claimed invention. Claim 32 defines “reacting the OPA in the test sample with an amount of a salt of bisulfite in a first reacting step...wherein the first reacting step occurs in the presence of the compound having an amino group....” The combination does not teach this step. Rather than two reactions as claimed by Applicants, the combination requires three reactions as described in Wu at column 2, lines 39 to 52. The second reaction produces the sodium glycinate which the Examiner has analogized to the present claimed second reactant (compound having an amino group). Since this is produced as a result of the first reaction, it is not present during the first reaction, rather it is formed as a product of the first reaction. These are method claims involving a two step reaction which the Examiner seeks to find obvious through a three step reaction. Witanski et al. and Wu cannot make obvious Applicants’ claimed method.

Applicants submit that the Examiner has failed to establish anticipation or a prima facie case of obviousness and request withdrawal of the rejections and allowance of the claims.

Respectfully submitted,

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Appendix
Claims on Appeal

1. A method of determining the presence of a point of interest of an aldehyde in a test sample using a first reactant capable of reacting with a carbonyl group of the aldehyde and a second reactant comprising a compound having an amino group and which is capable of reacting with the aldehyde to produce a color change, the method comprising the steps of:

in a first reacting step, in the presence of the second reactant reacting the aldehyde in the test sample with an amount of the first reactant sufficient to react with the aldehyde to the point of interest;

in a second reacting step, reacting the second reactant with any remaining aldehyde in the test sample to produce a first color; and

determining the presence of an excess of aldehyde in the test sample to the point of interest by observation of a final color of the test sample.

2. The method of claim 1, wherein the compound having an amino group is an amino acid.

3. The method of claim 2, wherein the amino acid is glycine.

4. The method of claim 2, wherein the amino acid is lysine.

5. The method of claim 1, wherein the second reactant is selected from the group consisting of a salt of bisulfite, a salt of cyanide, hydrazine, and hydroxylamine.

6. The method of claim 1, wherein the aldehyde comprises a germicide.

7. The method of claim 6, wherein the germicide is selected from the group consisting of OPA, glutaraldehyde, and formaldehyde.

10. The method of claim 1, wherein the step of reacting the aldehyde with the first reactant produces a second color.

11. The method of claim 1, wherein less than 1% of the aldehyde remains after the first reacting step when the amount of aldehyde in the test sample is less than the point of interest.

12. The method of claim 1 further comprising drawing up a fixed volume of an aldehyde-containing test sample before or during the first reacting step.

13. The method of claim 12 further comprising loading the fixed volume to a measuring device having a gas or vapor permeable but liquid impermeable membrane.

14. The method of claim 12 further comprising loading the fixed volume to a measuring device containing said compound for the first reacting step and said compound for the second reacting step.

30. A method of determining the presence of a point of interest of an aldehyde comprising the steps of:

reacting the aldehyde with an amount of a compound that reacts with a carbonyl group of the aldehyde in a first reacting step, wherein said amount is sufficient to react with the aldehyde to the point of interest to produce a first color;

reacting a compound having an amino group with any remaining aldehyde in a second reacting step, the compound being one that reacts with the aldehyde to produce a second color; and

determining the presence of an excess of aldehyde in a test solution to the point of interest by observation of a final color of a test solution,

wherein the first reacting step occurs in the presence of the compound having an amino group.

32. A method of determining the presence of a point of interest of OPA in a test sample comprising the steps of:

reacting the OPA in the test sample with an amount of a salt of bisulfite in a first reacting step, wherein said amount is sufficient to react with the OPA to the point of interest to produce a first color;

reacting a compound having an amino group with any remaining OPA in the test sample in a second reacting step, the compound being one that reacts with the OPA to produce a second color; and

determining the presence of an excess of OPA in the test sample to the point of interest by observation of a final color of the test sample,

wherein the first reacting step occurs in the presence of the compound having an amino group.

33. The method of claim 32, wherein the first reacting step is kinetically and thermodynamically favored over the second reacting step.



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(Date)

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June 2, 2005

(Date of Signature)

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

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Dear Sir:

Attached is an Appeal Brief for the above-captioned patent application.

Please charge Deposit Account No. 10-0750/ASP-8/ACF in the name of Johnson & Johnson in the amount of \$500.00, representing the cost of filing a Brief on Appeal in the above-captioned matter.

The Commissioner is hereby authorized to charge any additional fees which may be required to Account No. 10-0750/ASP-8/ACF. This Authorization is being submitted in triplicate.

Respectfully submitted,

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